

**PROPOSED**  
**MEETING OUTLINE**

- I. **Announce dates: October 28 & 29, 1998.** The Office of Surveillance and Biometrics is planning an Outside Leveraging Seminar for late October. **Outside Leveraging:** is the term we have adopted to describe the creation of relationships and/or formal agreements with others outside FDA/CDRH to obtain services/support for little or no monetary exchange. These services will support our OSB mission.

As federal budgets get smaller and our public health missions increase in size and complexity, we in government must become more creative about discovering new methods that allow us to operate efficiently and still meet our responsibility to protect the public health. One way to do this is to call upon academia, professional and standard setting associations, other regulators, the health care community, trade groups, consumer advocates, private industry and others with whom we share an interest and responsibility for protecting the public health.

While we have had some partnerships with these groups, it is our believe that there are others who have capabilities, information, influence and mechanisms which they are willing to share with us. This would allow us to multiply the positive results of our joint efforts and focus our limited federal resources in the narrow areas which are exclusively the government's responsibility.

The purpose of the seminar is for our employees to hear about creative successes and lessons learned by some of the pioneers in outside leveraging and then to apply this knowledge to explore the possibilities for outside leveraging in our office.

- II. **Detail on Seminar.** Oct 28th, Day 1 of the Seminar, will be a collection of speakers who have done some form of outside leveraging. We are in the process of contacting potential speakers to identify relevant cases we think would be of most interest to OSB.

October 29th, Day 2 of the Seminar, will afford OSB staff the opportunity to work in small groups to explore specific Outside Leveraging opportunities that OSB might want to pursue. The knowledge we have gained from the speakers will hopefully help us to learn from both their successes and mistakes so we make our own decisions more wisely about potential pilot OL projects. We plan to invite a couple of people from each Office of CDRH to join us for the first day of the Seminar to foster understanding and support for the OL projects we decide to pursue.

- III. **Linkage to the Strategic Plan.** This effort is being pursued in support of Goal 3, Strategy 3.4, which states "We will negotiate and implement with outside groups more efficient surveillance activities, placing a larger responsibility on them". The objective is to use OL to improve the quality and/or quantity of postmarket surveillance / research which can be accomplished within our existing resources. We would like staff to have

the opportunity to work on pilot projects which they identified and contributed. If you have a good idea you might also want to nominate the other members of the pilot team with whom you'd particularly like to work. An additional benefit of participating in this effort may be an opportunity to publish the results if your pilot proves to be particularly interesting or beneficial.

#### **IV. Examples and Explanations.**

Examples of OL in other agencies include Customs working with carriers to catch drug smuggling or firms and employees conducting inspections for OSHA. In CDRH, outside contributions to the standards activities account for 27 person years of work each year!

The range of examples in OL progress from something as simple as establishing collegial relationships with others to get things done more easily or to gain access to information (often called “partnering”) all the way to actively reducing the amount of work the government has to do because someone else performs a service at no cost. We’ve probably enjoyed more successes at the collegial relationship level than we have at the “offloading work” end of the spectrum.

For this OL Seminar we’d like to primarily focus on ways to lighten our workload, freeing us up to expend our precious human resources on the things that we are uniquely qualified to do. We know from the data gathered by the NTL students that there is fear and apprehension about the motivation for this. We assure you, this is NOT intended to eliminate anyone’s job. It IS intended to make sure we use our human talents to work on the most important things. There’s more than enough work to go around for everyone to continue to contribute in meaningful ways. Our mission continues to grow and our staff size doesn’t. If we don’t lay the groundwork to do things differently, we’ll be overwhelmed with work and public health will ultimately suffer.

#### **V. What we need from you.**

1.) Think about potential OL projects. Here are two examples:

- We know two researchers want to work with OSB to share device experience data similar to what we collect in the MDR system.
- We are starting to use marketing data to augment postmarket surveillance studies.

If you have a good idea, please share it with someone on the committee. Pat Spitzig (4-2483), Carol Herman (4-0834), Dan McGunagle (4-0643) and Suzanne Rich (4-2581) are on the committee.

We have developed some initial criteria for choosing potential OL projects that you may want to include in your thinking:

- a. There’s a real payoff in saved money or time (cost-benefit).
- b. The organization with which we’ll be attempting “hand-off” already has at least a neutral, if not positive, relationship with OSB/CDRH.
- c. The “process owners” inside OSB are supportive, or at least not hostile, to the concept of OL.
- d. The issue being considered is not one which is currently “politically charged.”

- 2) Consider attending the first day of the seminar to hear from those who have done this before. We'll be putting out an Agenda for the seminar about a week before the event. We're planning on having it in Room 120S so that we can maximize staff opportunity for attendance. We're also planning to videotape speakers for later use.
- 3) Volunteer or be willing to serve if invited to join a specific pilot OL team which will work on day two of the OL Seminar and for about 4 to 6 weeks after the meeting to fully explore the potential of particular OL opportunities for OSB.
- 4) Let the OL Committee know, ASAP, if you know of a good example of OL that we might want to include in our screening of potential speakers or if there is someone specific in CDRH that you think we should invite to the first day of the Seminar.
- 5) Mention this seminar to others in the Center whom you know have an interest in this subject.

#### **VI. Questions and Answers.**

Please feel free to direct questions to Pat and other members of the committee. Thanks for your interest. See you at